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Pesticide Assessment Guidelines, Subdivision D
Product Chemistry. Series 61-4
Addendum 1 on Data Reporting

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See also PB83-153890.

The starting point of any exposure assessment is the identification of the composition of the substance. The composition information that EPA requires for pesticides is called Product Chemistry data. Primarily, the information provides the identity of the chemical or chemicals involved. These data include information on the manufacturing process, chemical analysis of the active ingredient, certified limits for the ingredients in a product and analytical methods to determine the composition of the pesticide. The Agency evaluates the composition data to determine whether impurities could constitute a significant component of the residue in food and feed. The Data Reporting Guideline (DRG) is designed to aid the manufacturer/registrant/petitioner in the data/information collection/organization process.

KEYWORDS: *Pesticides, *Guidelines, *Federal Food Drug and Cosmetic Act.

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PESTICIDE ASSESSMENT GUIDELINES

SUBDIVISION D

PRODUCT CHEMISTRY

Series 61, 62, 63, and 64

ADDENDUM 1 ON DATA REPORTING

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Subdivision D - Product Chemistry

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PESTICIDE ASSESSMENT GUIDELINES

PRODUCT CHEMISTRY

Subdivision D, Series 61-64

DATA REPORTING

INTRODUCTION

A. Background

The starting point of any exposure assessment is the identification of the composition of the substance. The composition information that EPA requires for pesticides is called Product Chemistry data. Primarily, this information provides the identity of the chemical or chemicals involved. These data include information on the manufacturing process, chemical analysis of the active ingredient, certified limits for the ingredients in a product and analytical methods to determine the composition of the pesticide. The Agency evaluates the composition data to determine whether impurities could constitute a significant component of the residue in food and feed.

B. Purpose

Product chemistry profiles of a pesticide product are required by 40 CFR 158.120 to support its registration or reregistration.

Certain product chemistry information is also required when petitions for tolerances are submitted in conjunction with section(s) 408/409 of the Federal Food, Drug and Cosmetic Act.

Subdivision D of the EPA Pesticide Assessment Guidelines [§61-64] provide information to aid the manufacturer/registrant/petitioner in providing an acceptable product chemistry profile for a pesticide product.

Product chemistry data should answer the question: What is the chemical nature of the pesticide product for which registration/tolerance establishment is being considered.

C. Objective

This Data Reporting Guideline (DRG) is designed to aid the manufacturer/registrant/petitioner in the data/information collection/organization process. Data submitters are encouraged to produce complete reports for efficient review by the Agency. It pertains to organizing and presenting the substance of the data report. PR Notice 86-5, effective on November 1, 1986 and available from the Office of Pesticide Programs,

US EPA, pertains to physical formatting of reports (which are referred to as "studies") and submittal packages. Some of its requirements are mandatory.

RESPONSE TO PUBLIC COMMENTS

The purpose of this section is to acknowledge and address the concerns expressed in the letters of comment received by the Agency in response to the public notice in FEDERAL REGISTER, Volume 52, No. 57, pp. 9536-9537, March 25, 1987.

This addendum to the Pesticide Assessment Guidelines [Subdivision D] is to be considered an all-encompassing document. EPA recognizes there are sections in the addendums which do not apply in all cases. Therefore registrants should exercise scientific judgement in deciding which portions are germane to a specific data submission.

This Data Reporting Guideline is not intended to introduce new data requirements or revisions into the Pesticide Assessment Guidelines [Subdivision D] nor is it intended for use by Agency data reviewers as a mere checklist. It is intended to clarify ambiguities in interpretation of those existing Guidelines, and to organize the submission of data to facilitate the review process.

The Residue Chemistry Branch (RCB) has reviewed the two responses submitted by the registrants and based on their comments, RCB is of the opinion that no changes are necessary at this time. With regard to the questions on whether a separate analytical method report needs to be written for each test method utilized in the course of a study and whether the absolute limit of detectability needs to be provided, a description of each separate analytical method used in the study and its limit of detectability should be provided in a study report.

At the time of publication of this document, draft Good Laboratory Practices (GLP) regulations covering chemistry studies were being reviewed by the public (52 FR 48920, December 28, 1987). The registrant/petitioner is advised to follow the Agency's progress in finalizing these GLP.

GUIDELINE

The manufacturer's/registrant's/petitioner's reports should include all information necessary to provide complete and accurate topical discussions of the pesticide product: the identity of its active ingredient, impurities and intentionally added ingredients, how it is manufactured, how it may be detected or measured, and how it should be handled and packaged. (The latter two requirements do not necessarily pertain to petitions for tolerances.)

TITLE/COVER PAGE

Title page and additional documentation requirements (i.e. requirements for data submission and statements of data confidentiality claims), if relevant to the study report, should precede the content of the study formatted below. These requirements are described in PR Notice 86-5 published by the Office of Pesticide Programs on July 29, 1986.

TABLE OF CONTENTS

I. INTRODUCTION AND SUMMARY

A. Scope: Procedure/tests used (including sources).

B. Principles of the procedure/test used including any references which may be applicable.

II. MATERIALS AND METHODS[1/]

A. Equipment (list and describe);

B. Reagents and Standards (if applicable):[1/] List and describe source and preparation;

C. Procedures: Detailed stepwise description of procedure employed in test;

D. Instrumentation: Detailed description of equipment employed in the test;

E. Methods of calculation (if applicable); and

F. Other: Any and all additional information that the registrant considers appropriate and relevant.

III. RESULTS AND DISCUSSION: (Describe outcome of the test.)

A. Detailed description of the manufacturing process;

B. Names and addresses of suppliers of beginning materials;

C. Discussion of formation of impurities;

D. Preliminary analyses of five production batches;[1/]

E. Certification of limits of active ingredient and impurities submitted on Form EPA 8570-4 (Rev. 2/85);[1/]

F. Discussion of analytical methods to verify certified limits (including validation data);[1/]

G. Physical and chemical properties (including descriptions of test methods); and

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1/ Submissions in support of Topics §62-1, 62-2, and 62-3 should follow Residue Chemistry Series 171-4: Analytical Methods, Addendum on Data Reporting, available from the National Technical Information Service, order number PB86-248192.

H. Submittal of samples (if required by the Agency).

IV. CONCLUSIONS

Discussion of adequacy of procedures or tests as well as whether the results provide acceptable accuracy and precision. Discuss any other points which may have a bearing on the information/data provided.

V. CERTIFICATION

Certification of authenticity by the study director (including signature, typed name, title, affiliations, address, telephone number, and date).

VI. TABLES AND FIGURES (where appropriate)

VII. REFERENCES

VIII. APPENDICES

Representative chromatograms, etc., or any other relevant material not fitting in any of the other sections of a report.